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| Not for Submission under 57 OF R 1.55,                       | Examiner Name             | Andri | ae M. Holt |  |
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| 1  | KING, M. et al., "Mucomodulator therapy in cystic fibrosis: balancing mucus clearability against the spread of airborne pathogens", Pediatr. Pulmonol., 2004, Vol. 37, pages 77-79.   |  |
|----|---|--|
| 2  | ZAHM, J.M. et al., "The role of mucus sol phase in clearance by simulated cough", Biorheology, 1989, Vol. 26, pages 747-752.  |  |
| 3  | RAYNAL, B.D.E. et al., "Calcium-dependent protein interactions in MUC5B provide reversible cross-links in salivary mucus", J. Biol. Chem., 2003, Vol. 278, No. 31, pages 28703-28710.   |  |
| 4  | KWANG, H.K. et al., "Inhibition of mucin release from airway goblet cells by polycationic peptides", Am. J. Physiol-lung, 1999, Vol 277, pages 811-815.   |  |
| 5  | LINDEMANN, R.A., "Bacterial activation of human natural killer cells: role of cell surface lipopolysaccharide", Infect. Immun., 1988, Vol. 56, No. 5, pages 1301-1308.  |  |
| 6  | ZAYAS, G. et al., "A new paradigm in respiratory hygiene: increasing the cohesivity of airway secretions to improve cough interaction and reduce aerosol dispersion", BMC Pulmonary Medicine, 2005, Vol. 5, No. 11, pp. 1-12. |  |
| 7  | KING, M., "Mucus and its role in airway clearance and cytoprotection", Airways and Lung Defence, Ch. 35, pp. 409-416.   |  |
| 8  | ZAYAS, G. et al., "A new paradigm in respiratory hygiene: modulating respiratory secretions to contain cough bioaerosol without affecting mucus clearance", BMC Pulmonary Medicine 2007, 7:11, 1-13.                          |  |
| 9  | RUBIN, Bruce K., "The Pharmacologic Approach to Airway Clearance: Mucoactive Agents", Wake Forest University School of Medicine, Paediatr. Resv., 2006.   |  |
| 10 | SHIBUYA, Yasuhiro, et al., "Effect of osmolality on Mucociliary Transportability and Rheology of Cystic Fibrosis and Bronchiectasis Sputum", Respirology 2003, 8, pp. 181-185.  |  |
| 11 | FULORIA, M., et al., "Evaluating the Efficacy of Mucoactive Aerosol Therapy", Respir. Care 2000, Vol. 45, No. 7, pp. 889.873  |  |

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|   | 12 | KING, M. et al., "Clerance of mucus by simulated cough", J Appl Physiocl 1985; 58: 1776-1782.  |  |
|---|----|--|--|
|   | 13 | JEANNERET-GROSJEAN et al., "Sampling techniques and rheology of human bronchial mucus", Am Rev Respir Dis 1988, 137, 707-710.  |  |
|   | 14 | RUBIN, BK et al., "Mucus-depleted frog palate as a model for the study of mucociliary clerance", J Appl Physiol 1990; 69: 424-429.   |  |
|   | 15 | TOMKIEWICZ, RP et al., "Amilioride inhalation therapy in cystic fibrosis: Influence on ion content, hydration and rheology of sputum", Am Rev Respir Dis 1993: 148: 1002-1007.   |  |
|   | 16 | HARDY, JG et al., "Lung deposition of a Nacystelyn metered dose inhaler formulation", J Aersol Med 1993;6:37-34.   |  |
|   | 17 | KING, M et al., "Relationship with clearance funtions", Chapter 7 of: Takishima T, Shimura S, eds. Airway Secretion: Phusiological Bases for the Control of Mucus Hypersecretion (Lung Biology in Health and Disease Series) New York: Marcel Dekker, 1994, 283-314. |  |
|   | 18 | FENG, W et al., "Improved clearability of cystic fibrosis sputum with dextran treatment in vitro", Am J Respir Crit Care Med 1998; 157: 710-714.   |  |
|   | 19 | KING, M et al., "The Evolution of the frog palate model from mucocilliary clearance", In: Baum G. ed. Cilia, Mucus and Mucocilliary Interactions. New York: Marcel Dekker, 1998, 191-201.  |  |
| Ī | 20 | FINLAY, WH et al., "Lung delivery of aerosolized dextran" Am J Respir Crit Care Med 2000; 161:91-97.   |  |
|   | 21 | VANDERBIST, F et al., "Deposition of nacystelyn from a dry powder inhaler in healthy volunteers and cystic fibrosis patients", Drug Dev Ind Pharm 2001; 27:205-12.   |  |
|   | 22 | KING, M et al., "Pharmacological apporaches to discovery and development of new mucolytic agents", Advanced Drug<br>Delivery Review 2002;54:1475-1490.   |  |

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| 23   | KING, M., "Mucus, mucocilliary clearance and coughing", In:Bates DV. Respiratory Function in Disease, 3rd ed. Philiadelphia: Saunders, 1989: 69-78.  |  |
|------|--|--|
| 24   | KING, M., "Role of Mucus viscoelasticity in cough clearance", Biorheology 1987: 24:589-597.  |  |
| 25   | ZAYAS, JG et al., "Tracheal mucus rheology in patients undergoing diagnostics bronchoscopy: Interrelations with smoking and cancer", Am Rev Respir Dis 1990; 141: 1107-1113.   |  |
| 26   | WANNER, A et al., "Mucocillary clearance in the airways", Am J Respir Crite Care Med 1996; 154: 1868-1902.   |  |
| 27   | KING, M et al., "Mucus physiology and pathophysiology:Therapuetic aspects", Chapter 13 of: Derenne JP, Whitelaw WA Similowski T, eds. Actue Respiratory Failure in COPD (Lung Biology in Health and Disease Series). New York: Marcel Dekker, 1996: 391-411. |  |
| 28   | KING, M et al., "Mucus controlling agents: Past and present", IN:RAu JL, ed. Aerosolized Drugs for the Respiratory Tract. Respir Caree Clinics N Amer 1999: 575-594.   |  |
| 29   | KING, M et al., "Pharmacological approaches to discovery and development of new mucolytic agents", Advanced Drug Delivery Reviews 2002; 54: 1475-1490.   |  |
| 30   | KING, M., "Magnectic Microrheometer", In: Baraga PC, Allegra L., eds. Methods in Bronchial Mucology. New York: Raven Press, 1988, 73-83.   |  |
| 31   | OHTAKE, K et al., "Analysis of transient and reversible effects of poly-L-arginine on the in vivo nasal absorption of FITC-dextran in rats", Journal of Controlled Release 82, 2002, 263-275.  |  |
| 32   | MARRIOTT, C et al., "Changes in the Gel Properties of Tracheal Mucus Induced by Divalent Cations", Biorheology Vol. 16, pp. 331-337, 1979.   |  |
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